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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name:	Embolectomy Catheter
Product Trade Name:	PRONTO™ Short Extraction Catheter
Classification Name:	Unclassified Product Code, DXE
Manufacturer:	Vascular Solutions, Inc. 6464 Sycamore Court Minneapolis, Minnesota 55369
Establishment Registration:	2134812
Contact:	Sara L. Coon Senior Regulatory Affairs Associate (763) 656-4300 phone (763) 656-4250 fax
Performance Standards:	No performance standards have been developed under section 514 for this device.

Device Description:

The Pronto Short Extraction Catheter is a dual lumen catheter with related accessories. The extraction lumen allows for the aspiration and removal of embolic material (thrombus/debris) using the included syringes, guidewire, and extension line with stopcock. The catheter has a rounded distal tip with a protected, sloped opening of the extraction lumen to facilitate advancement of the catheter into the blood vessels or synthetic grafts and to maximize extraction of thrombus through the extraction lumen. Incorporated within the catheter distal tip is a non-blood contacting radiopaque marker for fluoroscopic visualization. The catheter has an approximate outer diameter of 0.078 inches, allowing delivery through standard 6Fr introducer sheath. The catheter is an over the wire design. The smaller (wire) lumen of the catheter is able to accommodate guide wires that are ≤0.018" in diameter. The catheter will be available in working lengths of 40 to 65 cm. The proximal end of the catheter incorporates a y-junction luer adapter to facilitate the attachment of the catheter to the included extension line, stopcock, and two syringes. A 74μm filter basket and a 0.018"/80cm straight guidewire (not identified in the schematic below) are included for assistance in the thrombus removal procedure. The filter basket can be used to filter the blood removed during the procedure for laboratory analysis of thrombus. The straight guidewire will be provided packaged and sterile from Galt Medical (K021990). The Pronto Short is provided sterile and is intended for single use only.

Intended Use:

The Pronto™ Short Extraction Catheter is indicated for the removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system and the removal/aspiration of thrombus from clotted synthetic dialysis grafts and arterio-venous fistulas.

Summary of Non-Clinical Testing:
Testing conducted included assessments of the design verification of the Pronto Short Extraction Catheter along with biocompatibility assessments. The results of this battery of tests confirmed the suitability of the Pronto Short Extraction Catheter for its intended use.

Summary of Clinical Testing:
No clinical evaluations of this product have been conducted.

Predicate Devices:
The Pronto Short Extraction Catheter is similar in intended use to the Cordis 7Fr Hydrolyser Thrombectomy Catheter, the XTD Thrombectomy Catheter, the Medtronic Export Aspiration Catheter, and the Vascular Solutions, Inc. Pronto Extraction Catheter.

Conclusions:
The Pronto Short Extraction Catheter is substantially equivalent to Cordis 7Fr Hydrolyser Thrombectomy Catheter, the XTD Thrombectomy Catheter, the Medtronic Export Aspiration Catheter, and the Vascular Solutions, Inc. Pronto Extraction Catheter. The testing performed confirms that the Pronto Short Extraction Catheter will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 - 2005

Vascular Solutions, Inc.
c/o Ms. Sara L. Coon
Senior Regulatory Affairs Associate
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369

Re: K051193
Trade Name: Pronto Short Embolectomy Catheter
Regulation Number: 21CFR §870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: II (two)
Product Code: DXE
Dated: May 6, 2005
Received: May 10, 2005

Dear Ms. Coon;

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number: K051193

Device Name: Vascular Solutions Pronto™ Short Extraction Catheter

Indications for Use: The Pronto™ Short Extraction Catheter is indicated for:

- the removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system.
- the removal/aspiration of thrombus from clotted synthetic dialysis grafts and arterio-venous fistulas.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051193